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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,723	01/17/2001	Yasuo Koishihara	53466/295	4861

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FOLEY AND LARDNER
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WASHINGTON, DC 20007

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/22/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,723

Applicant(s)

Koishihara

Examiner

G.R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above, claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 and 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

SUPPLEMENTAL DETAILED ACTION

1. Applicant's election with traverse of the species B cells and autoimmune disease, in Paper No. 20, filed 3/11/03, is acknowledged. Applicant argues that both lymphocyte subsets are implicated in autoimmune diseases.

These argument are not found persuasive for the following reasons. While B cells and T cells may both be implicated in autoimmune disease, they function through different mechanisms on different tissues in different ways in different diseases. As such, restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

2. Claim 14 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species of the elected invention.

Claims 13 and 15-24 are being acted upon.

3. The Abstract is objected to because it comprises multiple paragraphs.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the laboratory designation "HM1.24" is vague and indefinite as it is unclear precisely which antibody is encompassed by the claims. Laboratory designations cannot be held constant outside of the laboratory in which they are used, accordingly, the antibody of the instant invention is preferably identified by ATCC Accession Number.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same

and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the HM1.24 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. While a deposit was made under the provisions of the Budapest Treaty, said deposit alone is insufficient to fulfill the deposit requirement. In addition to the conditions under the Budapest Treaty, Applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Applicant's provision of these assurances through the submission of an appropriate declaration would obviate this rejection.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 13 and 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,298,420 (1994) in view of Goto, T., et al. (1994, IDS).

The '343 patent teaches a method of inhibiting B lymphocyte activation (by killing the lymphocyte) for the treatment of an autoimmune disease or a B cell cancer comprising administering a monoclonal antibody which binds B cells (see particularly column 1, lines 27-39 and column 6, lines 45-57).

The reference teaching differs from the claimed invention only in that it does not teach the use of the chimeric, humanized monoclonal antibody HM1.24 which binds SEQ ID NO:1.

Goto, T., et al. teaches the use of the chimeric, humanized monoclonal antibody HM1.24 which binds SEQ ID NO:1 on terminally differentiated B cells for the treatment of multiple myeloma (see particularly page 1922, column 2, paragraph 1 and page 1929, column 1 paragraph 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of inhibiting B lymphocyte activation (by killing the lymphocyte) for the treatment of an autoimmune disease, comprising administering a monoclonal antibody, as taught by the '343 patent, employing the humanized monoclonal antibody HM1.24 which binds SEQ ID NO:1, as taught by Goto, T., et al. as the specific monoclonal antibody. One of ordinary skill in the art at the time the invention was made would have been motivated to use the HM1.24 because said antibody was known to selectively bind terminally differentiated B cells, as taught by Goto, T., et al., and would thus, be an obvious choice for the elimination of said cells and the treatment of any disease (such as a B cell-mediated autoimmune disease) which said cells mediate. Note that the substitution of equivalents, in this instance different B cell-binding antibodies, is considered to be obvious.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
September 12, 2003